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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission	10

Application Number	10/538,903
Filing Date	June 14, 2005
First Named Inventor	Bernd HABER
Art Unit	
Examiner Name	
Attorney Docket Number	02/084 NUT

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☑ Other Enclosure(s) (please Identify below):
  English translation of the International Preliminary Examination Report

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	ProPat, L.L.C.		
Signature	Cathy Moore		
Printed name	Cathy R. Moore		
Date	Oct. 25, 2005	Reg. No.	45,764

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature	Claire Wygand		
Typed or printed name	Claire Wygand	Date	Oct. 25, 2005

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF TRANSMITTAL
OF COPIES OF TRANSLATION
OF THE INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY
(CHAPTER I OR CHAPTER II
OF THE PATENT COOPERATION TREATY)

(PCT Rule 72.2)

To:

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Date of mailing *(day/month/year)* 22 September 2005 (22.09.2005)	
Applicant's or agent's file reference 02/084 NUT	**IMPORTANT NOTIFICATION**
International application No. PCT/EP2003/014714	International filing date *(day/month/year)* 22 December 2003 (22.12.2003)
Applicant NUTRINOVA NUTRITION SPECIALTIES & FOOD INGEDIENTS GMBH et al	

1. **Transmittal of the translation to the applicant.**

The International Bureau transmits herewith a copy of the English translation made by the International Bureau of the international preliminary examination report established by the International Preliminary Examining Authority.

2. **Transmittal of the copy of the translation to the elected Offices.**

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following elected Offices requiring such translation:

AZ, CA, CH, CN, GH, KG, KP, KR, MK, MZ, RU, TM

The following elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, BA, BB, BG, BR, BY, BZ, CO, CR, CU, CZ, DK, DM, DZ, EA, EC, EE, EP, ES, FI, GB, GD, GE, GM, HR, HU, ID, IL, IN, IS, JP, KE, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MN, MW, MX, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, SC, SD, SE, SG, SK, SL, SY, TJ, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

3. **Reminder regarding translation into (one of) the official language(s) of the elected Office(s).**

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report.

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO
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Authorized officer

Ellen Moyse

Facsimile No.+41 22 338 89 75

Translation

PCT/EP2003/014714

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 02/084 NUT	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/EP2003/014714	International filing date (*day/month/year*) 22 December 2003 (22.12.2003)	Priority date (*day/month/year*) 24 December 2002 (24.12.2002)
International Patent Classification (IPC) or national classification and IPC A61K 31/202		
Applicant NUTRINOVA NUTRITION SPECIALTIES & FOOD INGEDIENTS GMBH		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 2 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
14 July 2004 (14.07.2004)	30 March 2005 (30.03.2005)
Name and mailing address of the IPEA/EP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/EP2003/014714

I. Basis of the report

1. With regard to the **elements** of the international application:*

☐ the international application as originally filed

☒ the description:

pages 1-12, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☒ the claims:

pages _____, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages 1-11, filed with the letter of 10 January 2005 (10.01.2005)

☐ the drawings:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the sequence listing part of the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/EP2003/014714

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 7-10

because:

☒ the said international application, or the said claims Nos. 7-10 relate to the following subject matter which does not require an international preliminary examination *(specify)*:

SEE SUPPLEMENTAL SHEET

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____ are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. _____.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: BOX III.1

Claims 7-10 relate to subject matter which, in the opinion of the Examining Authority, falls under PCT Rule 67.1(iv). Consequently, no opinion is established on the industrial applicability of the subject matter of these claims (PCT Article 34(4)(a)(ii)).

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-11	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-11	NO
Industrial applicability (IA)	Claims	1-6, 11	YES
	Claims		NO

2. Citations and explanations

1. In the PCT Contracting States, there are no uniform criteria for assessing the industrial applicability of Claims 7-10 in their present form. Patentability can also depend on the wording of the claims. The EPO, for example, does not recognise the industrial applicability of claims to the use of a compound in a medical treatment; it does, however, allow claims to the first use of a known compound in a medical treatment or to the use of such a compound in the manufacture of a drug for a new medical treatment.

2. This report makes reference to the following documents:

D1: EP-A-0 570 791 (CLINTEC NUTRITION CO), 24 November 1993 (1993-11-24)

D2: WO 00/53034 A (SOMAR CORP; TANIGUCHI MASA (JP); YAMAJI MUNETOSHI (JP)), 14 September 2000 (2000-09-14)

D3: US-A-5 723 446 (SCHMELKIN NANCY S ET AL), 3 March 1998 (1998-03-03)

D4: EP-A-1 295 538 (NUTRINOVA NUTRITION SPECIALTIE), 26 March 2003 (2003-03-26)

D5: EP-A-0 616 780 (COMPANIA GENERAL DEL

ALGARROBO), 28 September 1994 (1994-09-28), mentioned in the application

D6: DATABASE BIOSIS [Online] BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US; 1996 CONQUER JULIE A ET AL: "Supplementation with an algae source of docosahexaenoic acid increases (n-3) fatty acid status and alters selected risk factors for heart disease in vegetarian subjects", Database accession no. PREV199799383226 XP002277556 & JOURNAL OF NUTRITION, Vol. 126, No. 12, 1996, pages 3032-3039, ISSN: 0022-3166

D7: DATABASE BIOSIS [Online] BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US; 1994 GARG M L ET AL: "The importance of dietary eicosapentaenoic to docosahexaenoic acid ratio in modulation of serum lipid and arachidonic acid levels", Database accession no. PREV199497516500 XP002277557 & NUTRITION RESEARCH, Vol. 14, No. 10, 1994, pages 1575-1582, ISSN: 0271-5317

Novelty

3. The subject matter of

- independent product claims 1 and 5,
- independent process claim 6, and
- independent use claim 7
- independent use claim 11

is novel (PCT Article 33(2)). None of the documents D1-D4 directly and clearly discloses compositions which contain both water-insoluble carob fibres and omega-3 fatty acids in a concentration of 15% in relation to the totality of fatty acids (measured by the AOCS method). Nor is the production and use of

these compositions disclosed.

Inventive step

4. The subject matter of the present application does not involve an inventive step (PCT Article 33(3)).

4.1 D5 discloses the cholesterol-lowering effect of water-insoluble carob fibres (column 1, see also claim 1). The cholesterol-lowering effect of the omega-3 fatty acids EPA and DHA is likewise known from D6 or D7. EPA and DHA contain omega-3 fatty acids in a concentration of 100% in relation to the totality of fatty acids.

4.2 The objective technical problem is considered to be to provide an equally effective or improved cholesterol-lowering agent.

4.3 In the broadest claim, the problem is solved by combined preparations which contain water-insoluble carob fibres and omega-3 fatty acids in separate administration forms. Moreover, a composition is claimed which contains the two cholesterol-lowering substances, as well as its production and use.

4.4 No inventive step can be perceived therein, as a person skilled in the art would expect from the common administration of both active substances, which he would consider in order to solve the problem in question, at least the effect of the carob fibres or of the omega-3 fatty acids taken alone, if not an additive effect of both active substances.

4.5 Although a synergistic effect of the common

administration of the two active substances is extolled on page 10, last paragraph, of the application, no verifiable technical data which could substantiate this effect are described. Consequently, when assessing inventive step, the examiner proceeded from an at best additive effect, which cannot be considered inventive.